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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/471,255 | 12/23/1999 | JOSEE HAMEL | 55190-012 | 7195 |

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EXAMINER

PORTNER, VIRGINIA ALLEN

| | |
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| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/471,255

Applicant(s)

HAMEL ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 18-20, 25, 34, 35 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 18 is/are allowed.
- 6) ☐ Claim(s) 16, 19, 20, 25, 34, 35 and 39-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 16, 18-20, 25, 34-35, 39-42 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 20, 2004 has been entered.

Allowable Subject Matter

2. Claim 18 defines over the prior art of record and therefore defines allowable subject matter.

Response to Arguments

3. Applicant's arguments with respect to claims 16, ~~19~~ 18-20, 25, 34-35, 39-42 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

4. Claims 19-20, 25 and 35 are objected to because of the following informalities:

5. Claim 25 recites the phrase "at least 95% identity SEQ ID NO :2"; a transitional phrase is missing between the term 95% and identity.

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6. Claims 19-20 and 35 recite both open and closed language; the language used to claim Applicant's invention is not consistent through out the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 19, 20 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 19 recites both open and closed language; it is not clear what the scope of the claim is intended to be.

10. Claims 20 and 35 recite the phrase "having an amino acid sequence consisting of". The claims recites both open and closed language through the recitation of the term "having" which is language analogous to "comprising" and the term "consisting of" is close language.

11. What amino acids are included in the claimed polypeptides of claims 19, 20 and 35 selected from the amino acid sequence consisting of the recited ranges of amino acids?

Clarification is requested.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Please Note: In light of Applicant's definitions provided in the instant Specification defining the claimed polypeptides to include fragments, derivative, and analogs the following prior art rejections are being made of record.

12. Claims 16, 19-20, 25, 34, 35, 39, 40-42 rejected under 35 U.S.C. 102(e) as being anticipated by **Johnson et al (US Pat. 6,582,706**, effective filing date December 21, 1998) as evidenced by the sequence alignment of PhtE with BVH-3 amino acid sequence;
13. Johnson et al disclose the instantly claimed invention directed to an isolated polypeptide that shares at least 95% or 99% identity with an amino acid sequence of SEQ ID No 2, and would elicit a protective antistreptococcal immune response (see abstract, title, Figure 5, Sp36; Figure 6, Pht A, B D and E; col. 3, lines 20-42; alignment provided herewith (Swiss-Prot Blast search result shows sequence identity to be 96% over the full length protein as shown in Figure 5 of Johnson et al).
14. The polypeptides comprised an amino acid sequence that consists of the form HxxHxH (see col. 4, line 23-24 and lines 49-58, SEQ ID No 6, lines 44-47) which is a sequence of Instant sequence SEQ ID NO 2.
15. Additionally the polypeptides are disclosed for vaccine formulation with a pharmaceutically acceptable carrier and adjuvant (see col. 5, lines 48-65), and were specifically

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formulated together with Freund's complete or incomplete adjuvant (see col. 3, lines 43-67, figure 8).

The reference anticipates the instantly claimed invention as now claimed.

16. Claims 16, 19-20, 25, 34, 35, 39, 40-42 rejected under 35 U.S.C. 102(a) as being anticipated by WO98/18930 as evidenced by US 2004/0081662 A1.

17. WO98/18930 disclose the instantly claimed invention directed to an isolated polypeptide that shares at least 95% or 99% identity with an amino acid sequence of SEQ ID No 2, and would elicit a protective antistreptococcal immune response (see) US 2004/0081662 A1 that provides evidence that WO98' discloses PhtX proteins referred to as Sp36 and comprise the type II signal motif of LXXC (see US 2004/0081662 A1 [0019] and sequence alignments previously provided for WO 98 sequences SEQ Id Nos: 182, 56, 66 provided in paper numbers 17, and 26.

18. Additionally the polypeptides are disclosed for vaccine formulation with a pharmaceutically acceptable carrier and adjuvant, and were specifically formulated together with Freund's complete or incomplete adjuvant (see col. 3, lines 43-67, figure 8).

The reference anticipates the instantly claimed invention as now claimed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
September 27, 2004


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SUPERVISORY PATENT EXAMINER
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